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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/534,711	03/24/00	LIVINGSTON	P 53437-A-PCT-

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EXAMINER	
BANSAL,G	
ART UNIT	PAPER NUMBER
1642	3

DATE MAILED: 07/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/534,711	Wington et al
Examiner	**Group Art Unit**
Geetha P. Bansal	1642

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -3- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 3/24/00.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disp sition of Claims

☒ Claim(s) 1-16 is/are pending in the application.

Of the above claim(s)_____ is/are withdrawn from consideration.

☐ Claim(s)_____ is/are allowed.

☒ Claim(s) 1-16 is/are rejected.

☐ Claim(s)_____ is/are objected to.

☐ Claim(s)_____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on_____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on_____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)_____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:_____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s)._____

☒ Notice of Reference(s) Cited, PTO-892

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Interview Summary, PTO-413

☐ Notice of Informal Patent Application, PTO-152

☐ Other_____

Office Acti n Summary

DETAILED ACTION

1. Applicant's preliminary amendment filed March 24, 2000 (Paper No: 2/A) is acknowledged. Claims 2, 3, 9, 11-12, 14 have been amended and new claim 16 has been added. Accordingly, claims 1-16 are being examined.

Claim Rejections - 35 U.S.C. § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3.A. Claims 12-16 are rejected under 35 U.S.C.112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

3.B. Claims 12-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for eliciting an immune response against small cell lung cancer cells, does not reasonably provide enablement for all cancers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to a method of preventing and treating cancer by administering a fucosyl GM1 ganglioside conjugated to an immunogenic carrier, KLH and formulated with an adjuvant such that an antibody response is stimulated. An effective therapeutic or preventative protocol for the treatment or prevention of the formation of a tumor is subject to a number of factors which enter the picture beyond simply the specific binding of an antibody to the tumor cell line derived antigen. Demonstrating tumor antigen specificity in vitro cannot alone support the

predictability of the method for prevention of or treating said tumor growth through administration of either the antibody or T cell line expressing the appropriate specificity. The establishment and growth of a tumor is subject to variables beyond antigen specificity. The ability of a host to suppress and thereby prevent the tumor from establishing itself will vary depending upon factors such as the condition of the host, the type of tumor (rapidly proliferating or slowly proliferating) and the tumor burden. Thus, it is unpredictable as to the protective nature of the fucosyl GM1 ganglioside vaccine or immunogen. The specification merely provides results of a safety and immunogenicity study that indicates that antibodies of both IgM and IgG class were detected in the sera of volunteers. The study was done in patients who already had suffered from SCLC or were suffering from SCLC. It is not clear if there were antibodies existing in such patients (Grazyna et al, 1996 Immunol. Letters, vol 52 (2,3,) pgg. 89-93 teach that auto antibodies to fucosylated GM1 are present in patients) and whether the presence of such antibodies already indicates that therapeutic effects may not be achievable. No working examples have been provided that would guidance to one of skill in the art that the method of the inventions can be practised without undue experimentation. With respect to preventing and treating other cancers, there is no guidance or teaching provided to one of skill in the art as to the vast numbers of tumours/cancers that can be treated or prevented by this method. It appears that SCLC are the only cancers that the invention is drawn to. No clear evidence is available during a search in the literature data base that Fuc-GM1 ganglioside is a protective antigen in other types of cancers. Since these are also naturally occurring cell membrane antigens, it is not clear how a treatment or prevention can be envisioned. The specification also does not provide any guidance as to how to select or apply the methods to a subject in whom prevention can be monitored. How does a person of ordinary skill in the art select a candidate, immunize the candidate with the immunogen of the invention and then monitor if cancer has been prevented- because it is not a predictable phenomena as to which individual will definitely get cancer. For all the reasons above one of skill in the art cannot practice the claimed invention.

Claim Rejections - 35 U.S.C. § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jennemann et al (1996) and Vangsted et al (1994) in view of Kensil et al (1991). This same rekection may also apply to claims 12-16 if Applicant can successfully counter the 112, 1st para rejection set forth above.

Jennemann et al teach that optimal mode of vaccination with fucosylated ganglioside conjugated to KLH was able stimulate high antibody levels in the presence of an adjuvant such as MPL-A. Vangsted et al teach that Fuc GM1 is a target for ADCC. Jennemann et al do not teach adjuvants such as the claimed saponin, Quill A or QS-21. Kensil et al teach the use of the adjuvant derived from the bark of Qillaja saponaria Molina tree(from which QS-21 is derived) as efficient and safe adjuvants. It would have been primafacie obvious to a person of ordinary skill in the art at the time of the claimed invention to combine the teachings of Jennemann and Kensil

to arrive at the claimed invention as the prior art in combination provided the motivation and a reasonable expectation of success at obtaining an enhanced antibody production to immunization with Fuc-GM1 -KLH formulated in an adjuvant.

7. No claims are allowable.

8. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242 or (703) 305-3014.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Geetha P. Bansal whose telephone number is (703) 305-3955. The examiner can normally be reached on Mondays to Thursdays from 7:00am to 4:30pm and alternate Fridays from 7:00am to 3:30pm. A message may be left on the examiner's voice mail service.

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Anthony Caputa, can be reached on (703) 308- 4995.

11. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June 26, 2001

GEETHA P. BANSAL
PRIMARY EXAMINER